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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,252	03/21/2001	Nancy D. Hanson	180.0003 0103	6198

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EXAMINER

LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
1634	9

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/814,252	HANSON ET AL.
	Examiner	Art Unit
	Frank W Lu	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 2/25/2002.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1,2,4,5,7-11,17-21,24-27,30-38 and 49-57 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1,2,4,5,7-11,17-21,24-27,30-38 and 49-57 are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

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**DETAILED ACTION**

***Location of Application***

1. The Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1634.

***Election/Restriction***

2. After reviewing applicant's response on February 25, 2002, the office agreed to withdraw the Notice of Non-Compliant Amendment mailed on February 5, 2002. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 49, and 50, drawn to a diagnostic kit for detecting a TEM family beta-lactamase (claims 49 and 50) and related primers (claim 1), classified in class 536, subclass 24.33.
- II. Claims 2 and 51, drawn to a diagnostic kit for detecting a SHV family beta-lactamase(claim 51) and related primers (claim 2), classified in class 536, subclass 24.33.
- III. Claims 4-8, 52, and 53, drawn to a diagnostic kit for detecting an AmpC family beta-lactamase (claims 52 and 53) and related primers (claim 4-8), classified in class 536, subclass 24.33.

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- IV. Claims 8, 9, 54, and 55, drawn to a diagnostic kit for detecting a K1 family beta-lactamase (claims 54 and 55) and related primers (claims 8 and 9), classified in class 536, subclass 24.33.
- V. Claims 11, 56, and 57, drawn to a diagnostic kit for detecting a PSE1, PSE4, or CARB3 family beta-lactamase (claims 56 and 57) and related primers (claim 11), classified in class 536, subclass 24.33.
- VI. Claims 17-19, drawn to a method for identifying a beta-lactamase in a clinical sample, classified in class 435, subclass 91.2.
- VII. Claims 17, 20, and 21, drawn to a method for identifying a beta-lactamase in a clinical sample, classified in class 435, subclass 91.2.
- VIII. Claims 17, 24, and 25, drawn to a method for identifying a beta-lactamase in a clinical sample, classified in class 435, subclass 91.2.
- IX. Claims 17, 26, and 27, drawn to a method for identifying a beta-lactamase in a clinical sample, classified in class 435, subclass 91.2.
- X. Claims 17, 30, and 31, drawn to a method for identifying a beta-lactamase in a clinical sample, classified in class 435, subclass 91.2.
- XI. Claims 17, 32, and 33, drawn to a method for identifying a beta-lactamase in a clinical sample, classified in class 435, subclass 91.2.
- XII. Claims 17 and 34-36, drawn to a method for identifying a beta-lactamase in a clinical sample, classified in class 435, subclass 91.2.

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XIII. Claims 17, 37, and 38, drawn to a method for identifying a beta-lactamase in a clinical sample, classified in class 435, subclass 91.2.

3. The inventions are distinct, each from the other because of the following reasons:

Groups I and Groups II, III, IV, and V are distinct and independent inventions in that they are directed to different diagnostic kits and different primers . As a result, different and distinct searches will have to be performed. For example, the search required for Group I such as primers in Group I is not required for Groups II, III, IV, and V.

Group I and Groups VI, VII, VIII, XI, X, XI, XII, and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case , the product as claimed can be used in a materially different process of using that product such as a hybridization assay.

Groups II and Groups III, IV, and V are distinct and independent inventions in that they are directed to different diagnostic kits and different primers . As a result, different and distinct searches will have to be performed. For example, the search required for Group II such as primers in Group II is not required for Groups III, IV, and V.

Group II and Groups VI, VII, VIII, XI, X, XI, XII, and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

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process of using that product (MPEP § 806.05(h)). In the instant case , the product as claimed can be used in a materially different process of using that product such as a hybridization assay.

Groups III and Groups IV and V are distinct and independent inventions in that they are directed to different diagnostic kits and different primers . As a result, different and distinct searches will have to be performed. For example, the search required for Group III such as primers in Group III is not required for Groups IV and V.

Group III and Groups VI, VII, VIII, XI, X, XI, XII, and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case , the product as claimed can be used in a materially different process of using that product such as a hybridization assay.

Groups IV and V are distinct and independent inventions in that they are directed to different diagnostic kits and different primers . As a result, different and distinct searches will have to be performed. For example, the search required for Group IV such as primers in Group IV I is not required for Group V.

Group IV and Groups VI, VII, VIII, XI, X, XI, XII, and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

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process of using that product (MPEP § 806.05(h)). In the instant case , the product as claimed can be used in a materially different process of using that product such as a hybridization assay.

Group V and Groups VI, VII, VIII, XI, X, XI, XII, and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case , the product as claimed can be used in a materially different process of using that product such as a hybridization assay.

**Claim 17 links Groups VI, VII, VIII, XI, X, XI, XII, and XIII. The restriction requirement of the linked inventions is subject to the nonallowance of the linking claim(s), claim 17. For prior art that can be used to reject claim 17, see Leegaard *et al.*, (APMIS, 104, 302-306, 1996) and Vahaboglu *et al.*, (J. Clin. Microbiology, 36, 827-829, March 1998) (both references can be found in IDS). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer**

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**applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.**

5. Sequence Election Requirement Applicable to Groups I, II, III, IV, V, VI, VII, and XII.

The primers in Groups I, II, III, IV, V, VI, VII, and XII reads on patentably distinct SEQ ID Numbers. Each sequence is patentably distinct because the sequences are structurally unrelated sequences, and a further restriction is applied to each Group. Therefore, applicant must further elect a pair of primer for the examination (See MPEP 803.04). Applicant is advised that examination will be restricted to only elected SEQ ID NO. and should not to be construed as a species election.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

Frank Lu  
November 15, 2002



W. Gary Jones  
Supervisory Patent Examiner  
Technology Center 1600